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TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 00D:1278
Draft Guidance: Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment

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I. Women's Sexual Problems and "Female Sexual Dysfunction": Premature Language and Premature Solutions

Even before Viagra was approved in March, 1998, there was considerable commercial and media interest in drug products for women's sexuality. However, the FDA must resist a commercial tidal wave which is not scientifically or clinically justified, and where premature drug development and marketing will obscure complexities in the nature, extent, and causes of women's sexual problems.

A number of elements in the Draft Guidance Document acknowledge the current state of uncertainty in knowledge about women's sexual problems. Unlike the situation with men's erectile dysfunction, where, in 1992, a formal NIH Consensus Development Conference had produced an extensive scientific and clinical report, there has been no authoritative unbiased classification or epidemiology of women's sexual problems, no comprehensive overview of treatment strategies and outcomes, and no agreement on assessment methods.

In large part, the current uncertainty comes from the fact, as all who've written on this subject agree, that women's sexuality is inextricably tied to changing social and cultural realities, requiring careful multidisciplinary analysis. There are no universal biological norms in this field. Many women find the language of "achieving" orgasm to be offensive. Research has not been able to separate "desire" from "arousal." The most widely used classification of sexual problems, that found in the American Psychiatric Association's Diagnostic and

Statistical Manual, is generally considered inadequate as regards women's sexuality. Recent attempts to update and improve upon this nosology have been biased by pharmaceutical industry interests.

Thus, we recommend that an invitation to drug development in this area be postponed until systematic assessment of women's sexual needs can be conducted, and until appropriate multidisciplinary discussion can create agreement on language and methods.

II. Women's Sexual Satisfaction, Clinical Trial Endpoints, and Exclusion Criteria: Drug Trials and the Real World.

In the real world, women's sexual problems do not exist separate from their relationships and social context. Clinical experience and research demonstrate that women often come to adult sexual life with limited sexual knowledge, negative body image, the residue of negative past experiences, and confusion as to their sexual entitlements. Remedying sexual problems is impeded by embarrassment and fear of rejection. Women frequently evaluate the desire for and the pleasure and intimacy of physical sexual experience in relation to emotional issues such as safety and satisfying their partner. Subjective sexual arousal is linked as much to socially influenced emotions and meanings as to genital stimulation. Research suggests that orgasm, while valued, does not necessarily define sexual satisfaction for women. Because of gendered social reality, women's sexual development and experience cannot be reduced to biological function

One cannot simply assert (cf Sect. VI. in Guidance) that "the determination of successful and satisfactory sexual events should be made by the woman participating in the [clinical] trial, as opposed to her partner" if that conflicts with women's sexual experience in the real world. The FDA or the pharmaceutical industry may feel that women "should" create their own definitions of sexual success, but this flies in the face of research on female socialization and relationship dynamics. Even if sexual partners are not included in the research (a problematic decision, as it was in erectile dysfunction trials), the determination of what constitutes a "successful" sexual encounter is hardly a decision which can be made out of social context.

The inclusion and exclusion suggestions in Section III of the Draft Guidance Document bypass too many aspects of women's sexual reality. Excluding women from drug evaluation who acknowledge relationship difficulties or who are using medications which could affect sexual function precludes valid generalizations.

Excluding women's real-life complications is additionally problematic because of the current climate of direct-to-consumer advertising. Advertising budgets for sexuality drug products are growing exponentially, and current sexuality drug product advertisements appeal to romance, with images of dancing and embracing. Because of this climate, drug products for women's sexual problems must be tested on a broad range of women, using clinical endpoints which women themselves endorse. Simply importing a model of sexuality used in men's research is highly inappropriate.

Therefore, we believe that it is irresponsible to conduct narrow clinical trials, and we recommend that any product which will be advertised to help women's sexual lives be tested on a broad and diverse study population using clinical endpoints appropriate to women's lives.

III. Conclusion

Despite the immense recent media attention to industry-promoted claims about the disorder of "female sexual dysfunction," there is substantial professional controversy about the legitimacy of this language and perspective. Nothing now prevents studies on distressing urogenital or genitopelvic sexual symptoms associated with diseases like diabetes, "natural states" such as menopause, or connected with the use of many popular medications. Such information would be welcome as would safety and efficacy information on palliative remedies.

But, that is not the same as soliciting NDAs on a phenomenon, "female sexual dysfunction," which prematurely concretizes one view of women's sexual experience and problems. Contrary to the language of the guidance document, (cf. Sect. III), we do not feel that it is in women's best interests that trials be designed "to increase the likelihood of demonstrating a treatment effect." Rather, we recommend that further multidisciplinary research and discussion is needed to identify the realities of women's sexual health and well-being before clinical drug trials can be invited.

We recognize the complexities of these issues, and would be pleased to come to Washington to discuss how to make further work on women's sexual problems more inclusive and comprehensive.

Any replies will be distributed to all commentary signers by:
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